UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE BOSTON SCIENTIFIC	*	
CORPORATION	*	Master Case No. 05-11934-JLT
SECURITIES LITIGATION	*	

MEMORANDUM

June 21, 2007

TAURO, J.

Lead Plaintiff, the Public Employees' Retirement System of Mississippi ("PERS") brings this action against Boston Scientific Corporation ("BSC"), and its executives, James R. Tobin, Paul A. Laviolette, Fredericus A. Colen, Lawrence C. Best, Stephen F. Moreci, Robert MacLean, Peter M. Nicholas, Paul Sandman, and James H. Taylor, Jr. for (1) violations of Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and (2) violations of Section 20(a) of the Exchange Act. Defendants move to dismiss all counts. Presently at issue is Defendants' Motion to Dismiss [#50].

Background

The following background facts are taken as stated in Lead Plaintiff's Consolidated Amended Complaint ("CAC"), as well as publicly filed documents.[1]

Boston Scientific Corporation, headquartered in Natick, Massachusetts, manufactures medical device products in the areas of cardiovascular and endosurgery. Lead Plaintiff PERS brings this action on behalf of entities and individuals who purchased equity securities in Boston

[1] See In re Colonial Mortgage Bankers Corp., 324 F.3d 12, 19 (1st Cir. 2003) ("[M]atters of public record are fair game in adjudicating Rule 12(b)(6) motions, and a court's reference to such matters does not convert a motion to dismiss into a motion for summary judgment.").

Scientific between March 31, 2003, and August 23, 2005 (the "Class Period"). In its 102-page Consolidated Amended Complaint, Lead Plaintiff alleges that the Defendants made false statements and concealed material information about BSC from the investment community, causing the market price of the BSC's securities to artificially inflate during the Class Period, and enabling the individual defendants to enrich themselves by an amount in excess of $332 million.

Lead Plaintiff asserts that Defendants' material misstatements and omissions can be broken into four areas: (1) Civil lawsuit with Medinol Ltd. ("Medinol"); (2) Department of Justice ("DOJ") investigation; (3) rush of TAXUS stents to market; and (4) Food and Drug Administration ("FDA") investigations and warnings.

(1) Civil Lawsuit with Medinol

Lead Plaintiff alleges that Defendants artificially inflated BSC's stock price by purposefully misleading investors about the nature, scope and severity of ongoing litigation with Medinol–which settled after five years of litigation, and resulted in BSC paying Medinol $750 million.

In 1995, BSC entered into an agreement with Medinol in which BSC took a 22% interest in Medinol. Medinol agreed to be responsible for developing and manufacturing stents, and BSC agreed to bring the stents to the market.

In a 2001 lawsuit filed in the Southern District of New York (two years before the class period began), Medinol asserted that BSC had engaged in a "multi-year scheme to defraud" by trying to copy Medinol's stent designs.[2] BSC counter-claimed against Medinol for failing to meet BSC's stent demand requirements.

[2] CAC ¶ 57.

Lead Plaintiff alleges that in BSC's Report on Form 10-K for the year ending December 31, 2003, BSC failed to discuss the New York litigation in the narrative section of the reports and, instead, buried it deep within the report in a note.

The discussion of the Medinol litigation in BSC's annual Form 10-K is as follows:

> On April 5, 2001, Medinol Ltd. (Medinol) filed a complaint against the Company and certain of its current and former employees alleging breaches of contract, fraud and other claims. The suit was filed in the U.S. District Court for the Southern District of New York seeking monetary and injunctive relief. On April 26, 2001, Medinol amended its complaint to add claims alleging misappropriation of trade secrets in relation to the Company's Express(TM) stent development program. Medinol seeks monetary and injunctive relief, as well as an end to the Company's right to distribute Medinol stents and to gain access to certain Company intellectual property. On April 30, 2001, the Company answered and countersued Medinol and its principals, seeking monetary and injunctive relief.[3]

BSC's public filings set forth the Medinol litigation as a "risk." The public filings stated,

> Forward-looking statements discussed in the report include, but are not limited to, statements with respect to, and the Company's performance may be effected by:
> - The impact of stockholder, patent, product liability, Medinol Ltd. and other litigation . . . .[4]

This statement was misleading, Lead Plaintiff submits, because it understated the severity of the litigation. According to Lead Plaintiff, "[i]t was never a matter of whether the company would pay Medinol for the illegal conduct engaged in by individual Defendants Nicholas, Best, and others . . . It was only a question of when and how much."[5] In support of this claim, Lead

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[3] App. of Public Rs. Submitted in Supp. of Defs.' Mot. to Dismiss, Paper #53 (hereinafter App. Public Rs.), Ex. A. at Exhibit 13.1, p. 41; Ex. B at Exhibit 13.1, p. 67; Ex. C at p. 65.

[4] CAC ¶ 61.

[5] Id. ¶ 62.

Plaintiff notes that in 2000, Defendant Tobin admitted privately to Medinol officers that he was unaware when he joined BSC that he was involved with "such crooks" and that he was "ashamed to represent such a dishonest company."[6]

Lead Plaintiff asserts that Defendants made other misleading and false statements about the status of the Medinol litigation.

In an April 5, 2001, press release about the Medinol litigation, BSC Vice President of Corporate Communications Paul Donovan ("Donovan") said, "Medinol's complaint alleges breaches of contract, fraud and other claims . . . These claims have no merit."[7]

On April 11, 2001, Defendant Tobin at the Company's Annual Meeting of Securities Analysts said about the Medinol litigation,

> The bottom line about this lawsuit is that the party in the wrong is Medinol.
>
> - It was Medinol that could not or would not fill our orders . . .
> - It was Medinol that consistently refused to provide us with enough stents
> - It was Medinol that at least a dozen separate times threatened to cut off its supply of stents

This is all about leverage, plain and simple.[8]

In a July 22, 2003, meeting with analysts, Defendant Sandman said, in reference to the Medinol litigation, "I don't frankly think that theory [Medinol's trade secret theory] is going to hold up."[9]

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[6] CAC ¶¶ 57, 62.

[7] Id. ¶ 59.

[8] Id.

[9] Id. ¶ 63.

Lead Plaintiff says this statement was false because Defendant Sandman knew that Medinol's underlying theory would prevail.

On December 2, 2004, BSC spokesman Donovan, under the direction of Defendants Tobin and Nicholas, issued a press release in response to an eighty-four page Medinol litigation summary judgment ruling[10] issued that same day from the court in New York. The press release included the following language: "As the ruling states, this is essentially a breach of contract case, which alleges 'grandiose estimates of damage' that are unlikely to succeed."[11] Lead Plaintiff says this statement was false because at the time Defendants made positive statements about the Medinol litigation, they knew that insiders within the company had engaged in a scheme to defraud Medinol, and they knew that those acts exposed BSC to significant liability.

At a January 10, 2005, conference call with analysts, Defendant Tobin said in regards to the New York litigation, "Medinol, that thing has been brought down to this thing which is a contract dispute. So sooner or later that will get solved."[12]

At a June 15, 2005, Goldman Sachs Healthcare Conference, Defendant Best, in response to an inquiry asking for litigation updates, stated:

> We also have a Medinol case dealing with our failed partnership with Medinol back in 1995-96-97 around there, and it's not a patent issue, it's not [an] intellectual property issue, it's primarily a straight out contract, breach of contract issue. We're not before a jury, we're before a judge, and we expect to go to trial in the next 4 or 5 weeks I think.[13]

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[10] Medinol Ltd. v. Boston Scientific Corp., 346 F. Supp. 2d 575, 627 (S.D.N.Y. 2004).

[11] CAC ¶ 68.

[12] Id. ¶ 64.

[13] Id. ¶ 65.

Lead Plaintiff says this statement was misleading because when Defendant Best made this statement he knew as a result of ongoing settlement discussions that BSC was going to pay Medinol millions of dollars for the fraud that BSC had perpetrated on Medinol.

Settlement discussions with Medinol took place in early 2005.

On August 16, 2005, an Israeli newspaper reported the preliminary terms of the settlement as including a large payment to Medinol. The price of BSC securities then dropped 32 cents, or 1.30%.

On August 17, 2005, an analyst leaked the terms of the settlement on Bloomberg, and the stock dropped another 37¢ or 1.82%.

BSC ultimately settled with Medinol in September of 2005. In the settlement, BSC gave up its 22% equity interest in Medinol, paid Medinol $750 million and Medinol preserved for arbitration proceedings its intellectual property claims against BSC. In announcing the settlement, BSC spokesman Donovan said "[w]e're pleased to close this chapter, and put this matter behind us."[14]

Ultimately, the $750 million settlement was reflected in a special charge taken by the company which Defendant Best estimated cost shareholders about $.75 per share.

(2) Department of Justice Investigation

Lead Plaintiff asserts that the Defendants made material misrepresentations and omissions about an ongoing DOJ investigation.

In August 1998, more than four years before the class period, BSC introduced its "NORS" coronary stents. In October of that year, BSC voluntarily recalled certain of those

[14] Id. ¶ 72.

stents following reports of balloon leaks.

In November 1998, DOJ began an investigation of the NORS recall. The investigation concerned whether BSC "took an improper risk" in marketing its NORS stents, and whether BSC officials knowingly released adulterated medical devices into the marketplace. The investigation continued for many years, and both BSC and two of its senior officers were named as targets of the investigation.

Lead Plaintiff alleges that as part of the DOJ investigation, grand jury proceedings during the Class Period revealed that senior officials of BSC, including Defendant Nicholas, knew that the NORS stents had experienced a catastrophic failure rate in clinical trials, but continued shipping them, in total disregard of public safety.

Lead Plaintiff charges that Defendants misled the investment community by downplaying the gravity and merits of this investigation. During the class period, the DOJ investigation and the risk of an adverse outcome were mentioned in Boston Scientific's 10-K filings.[15] BSC's 10-K filings throughout the class period also disclosed that "[t]here can be no assurance that the [DOJ] investigation will result in an outcome favorable to the Company . . . ."[16] And BSC's SEC filings stated that the outcome of the DOJ investigation "may" adversely affect the company.

The annual Form 10-K for the years ending 2002, 2004 and 2005 stated that the company had "acted responsibly and appropriately" with respect to the matter under investigation.[17] Lead

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[15] See Id. ¶ 61 ("[T]he Company's performance may be effected by: . . . the ultimate outcome of the U.S. Department of Justice investigation.").

[16] App. Public Rs. Ex. A, p. 42, Ex. B, p. 68-69, Ex. C, p. 67.

[17] CAC ¶ 75.

Plaintiff maintains that these statements were false and that the Defendants knew they had acted neither responsibly nor appropriately.

As further proof that the Defendants acted neither responsibly nor appropriately, Lead Plaintiff points out that BSC executives (not the defendants) repeatedly asserted their Fifth Amendment privilege when being deposed as part of the Medinol litigation.

In February 2005, an expected settlement of the matter was announced. In June 2005, a civil settlement was reached in which BSC agreed to pay $74 million. Lead Plaintiff submits that this settlement adversely affected the market price of BSC's stock. The settlement did not involve any admission of liability or wrongdoing by BSC, and the DOJ did not bring any criminal charges against BSC or any of its officers.

After the settlement, BSC issued a June 24, 2005, press release in which Defendant Tobin announced, "We believe that Boston Scientific and its employees acted legally, responsibly and appropriately at all times."[18] Lead Plaintiff says this statement was false and misleading because the Defendants knew that they had not acted appropriately or responsibly. As further proof, Lead Plaintiff points to a June 24, 2005, DOJ press release:

> This case represents a failure by Boston Scientific to take the most appropriate steps in a timely manner to ensure that the devices it was distributing to hospitals performed properly.
> . . .
> The company identified the problem through its own internal testing and took a risk that those same problems would not occur in the marketplace. This type of behavior by a major medical device manufacturer is unacceptable.[19]

[18] Id. ¶ 83.

[19] Id. ¶ 84.

(3) Recall of TAXUS Stents

Lead Plaintiff asserts that while Boston Scientific was launching its new drug-eluting TAXUS stent during the Class Period, it knew and withheld information that the product was fraught with problems and was being released prematurely. Lead Plaintiff submits that BSC selectively disclosed positive news about TAXUS while hiding material information about problems with the product.

In September 2003, BSC released data showing the efficacy and safety of TAXUS, but did failed to disclose that it had received an FDA major deficiency letter raising concerns related to its manufacture.[20]

On March 4, 2004, the FDA approved the marketing and distribution of TAXUS in the United States. Lead Plaintiff asserts that BSC rushed TAXUS to market and trumpeted its immediate impact on BSC's effort to take over market share for stents.

The individual Defendants provided the investment community a "drum roll leading up to the FDA's approval of TAXUS which was deafening."[21] And by March 2004, this carefully orchestrated positive message about TAXUS caused the trading price of BSC securities to hit an all-time high on the New York Stock Exchange.

Prior to the release of TAXUS into the U.S. marketplace, BSC had received adverse reports out of Europe, where TAXUS had already been released.[22] Some European physicians were complaining that the balloon used to insert the stent would not deflate after insertion and

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[20] Id. ¶¶ 88-89.

[21] Id. ¶ 89.

[22] TAXUS was released in Europe in January of 2003. Id. ¶ 87. BSC received roughly forty complaints from the 350,000 TAXUS stents it released. Id. ¶ 93.

that the balloon was sticking. Lead Plaintiff says that Defendants minimized and misrepresented the problems they were hearing from the field.

Lead Plaintiff alleges that Defendants further downplayed the complaints in discussions with analysts. In an April 20, 2004 call with analysts, Defendant LaViolette said, "[t]his issue [problems with TAXUS] surfaced in the first few months and then as physicians got used to TAXUS, essentially all complaint activity subsided and if you look at international utilization today, and if you look at complaints for any kind of removal difficulty, there are virtually no ongoing complaints."[23]

In a Boston Globe article dated April 24, 2004, BSC spokesman Donovan said that the number of problem cases involving TAXUS was minor relative to the 84,000 TAXUS stents implanted in American patients since the FDA approved the device March 4, 2004. Donovan also said that a few doctors in Europe reported similar problems when TAXUS was initially approved for use there last year, but the complaints ended as doctors become more comfortable with the stents.

Lead Plaintiff asserts that Defendants knew at that time that the problems with TAXUS were much more significant, based on the complaints they had received from European doctors and the complaints which were rolling in as a result of the March 2004 TAXUS release in the United States.[24] Lead Plaintiff further submits that BSC covertly implemented a TAXUS manufacturing change to address the balloon deflation problem, but failed to disclose this change to the public.

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[23] CAC ¶ 93.

[24] Id. ¶ 95.

According to Lead Plaintiff, in April and May of 2004, Defendants simultaneously placed good news in the market about the rollout of TAXUS while stalling any meaningful disclosure about the complaints received about TAXUS. As the stock price rose, Lead Plaintiff alleges that the Defendants began to sell millions of dollars of BSC stock.

In its Report on Form 10-Q for the period ending March 31, 2004, which was filed with the SEC on May 7, 2004, BSC stated that its success with drug-eluting stents could be adversely impacted by "unexpected variations in clinical results or product performance," and disclosed that "[t]he Company is currently reviewing a limited number of reports related to balloon withdrawal difficulty during TAXUS angioplasty procedures."[25]

Four months after receiving FDA approval, on July 2, 2004, BSC announced its first recall of two lots of TAXUS stents, which constituted 200 stents. The company issued the following press release:

> FDA has received reports of one death and 16 serious injuries associated with balloon deflation. In addition, the agency has received eight reports of balloon malfunction that were not associated with patient injury.[26]

Lead Plaintiff says that the Company tried to minimize the problem by attributing it to only "two batches [of TAXUS stents] out of 1,200 and some we produced so far" and that BSC maintained that the problem had been addressed with a manufacturing change that had implemented before BSC launched TAXUS.[27]

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[25] Id. ¶ 93; App. Public Rs., Ex A at Exhibit 13.1, p. 15-16; Ex. B at Exhibit 13.1, p. 30-31; Ex. C, p. 15-16.

[26] CAC ¶ 97.

[27] Id. 98.

Lead Plaintiff notes that BSC did not disclose the TAXUS manufacturing change in its Form 10-Q for the Quarter ending March 31, 2004, which was filed with the SEC on May 7, 2004. But after the recall, BSC revealed the manufacturing change in its Form 10-Q filed with the SEC on August 9, 2004. Lead Plaintiff asserts that this manufacturing change was material information that the market had a right to know about.

On July 16, 2004, Boston Scientific expanded its recall to 85,000 TAXUS stents and 11,000 other stents. The stock dropped $3.09 per share or 7.6% to $37.40.

Throughout this period, the Defendants tried to reassure the market about the safety of the Company's products. On July 29, 2004, Defendant LaViolette said the Company had "identified and fixed the problem."[28] Lead Plaintiff says this was false, as demonstrated by a subsequent recall.

On August 4, 2004, BSC announced a further recall of 3,000 TAXUS stents. BSC stock promptly dropped $2.41 or 6.6%.

From July 2, 2004, when Defendants first disclosed the problems with TAXUS, to August 5, 2004, when Boston Scientific expanded the TAXUS recall for a second time, the stock price of Boston Scientific dropped 21%.

On August 4, 2004, Defendant LaViolette called the recall a "nuisance."[29] Lead Plaintiff maintains that this was far more than a "nuisance"–the faulty product had resulted in a number of serious injuries and the defective stents recall cost BSC $57 million.

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[28] Id. ¶ 101.

[29] Id.

(4) The FDA Investigations and Warnings

Lead Plaintiff asserts that Defendants made intentional, material misrepresentations and omissions about BSC's quality control.

The medical devices manufactured by BSC are subject to regulation by the FDA, and the FDA periodically conducts field inspections. Lead Plaintiff asserts that BSC touted the occasions in which it complied with FDA rules, but remained silent when it received bad news. For example, on September 8, 2004, BSC issued a press release announcing that the FDA had inspected its Galway, Ireland facility and reported no violations. And on April 5, 2005, a BSC press release touted its "rigorous laboratory testing."[30]

Between March 9 and April 7 of 2005, the FDA conducted an inspection of BSC's Watertown, Massachusetts manufacturing facility. On May 18, 2005, the FDA wrote BSC a letter, noting regulatory deficiencies at the Watertown facility. This letter, which was published on the FDA website on June 7, 2006, noted that BSC "fails to address specific systemwide corrective actions that are necessary to bring your facility into compliance."[31] The letter then stated that certain devices manufactured by BSC were adulterated and outlined "significant deficiencies" which the inspectors uncovered.[32] Lead Plaintiff asserts that this FDA letter was disseminated among BSC insiders, but that none of the individual Defendants publicly reported this regulatory warning. Defendant Moreci, who had been copied on the FDA letter, sold $1.4 million of BSC stock on May 31, 2005.

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[30] Id. ¶ 108.

[31] Id. ¶ 110.

[32] Id.

In a June 15, 2005, presentation to Goldman Sachs, Defendant Best did not disclose the FDA warning letter and told the audience that BSC "is really burdened today by its enormous success" and that "we basically have a set of cards that really are second to no one else."[33]

On August 1, 2005, BSC received a warning letter from the FDA concerning certain deficiencies at its Glens Falls, New York facility. This letter was also posted on the FDA website, although the actual date of posting is unknown. The FDA's letter informed BSC of violations found during the Glens Falls inspection and noted that "[t]hese violations cause the aforementioned medical devices at your firm to be adulterated . . . ."[34]

Lead Plaintiff charges that the Defendants made no effort to inform the investment community of this second letter,[35] and that BSC's website contained a material misrepresentation by describing the manufacturing facility at Glens Falls, New York as "world class."[36]

The Company's Report on Form 10-Q for the quarter ending June 30, 2005, which was

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[33] Id. ¶ 115.

[34] Id. ¶ 119.

[35] On August 16, 2005, Reuters published a news article that discussed this second FDA letter. The article noted that,

> in the latest FDA warning letter, dated Aug. 1, the agency said the company's reply was lacking. "Several responses provide little detail regarding how your firm will achieve the desired corrections," the agency said. Boston Scientific shares were off 25 cents to $28.15 on Tuesday on the New York Stock Exchange.
>
> The FDA sends dozens of warning letters each year. Many companies fix problems without further penalty, but the warnings can lead to product seizures, injunctions or fines.

Id. ¶ 122.

[36] Id. ¶ 119.

filed with the SEC on August 9, 2005, stated that the company was committed to "quality."[37] Lead Plaintiff says this was a false statement, as evidenced by the FDA warnings letters.

On August 10, 2005, Boston Scientific received a third warning letter from the FDA, this one related to a facility in Quincy, Massachusetts. The letter detailed "serious regulatory problems" at the Quincy facility.[38] The letter included the following warning:

> You should know that these serious violations of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of the product, or assessing civil money penalties.[39]

Defendants did not disclose this letter to the investment community. The letter was published on the FDA website on August 23, 2005. On August 23, 2005, TheStreet.com also reported the letter under the headline *FDA Scolds Boston Scientific*. In response to this news, Lead Plaintiff maintains that the price of Boston Scientific stock dropped $1.23 or 4.5% to $25.92. This was a 43.4% decline from BSC's class period high of $45.81 on April 5, 2004.

In Reports on Form 10-K filed with the SEC for the year ending December 31, 2003, BSC stated that "[t]he Company is committed to providing high quality products to its customers. To meet this commitment, the Company has implemented state-of-the-art quality systems and concepts throughout the organization."[40] Lead Plaintiff submits that this statement was untrue and misleading as demonstrated by the FDA warning letters.

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[37] Id. ¶ 116.

[38] Id. ¶ 121.

[39] Id.

[40] Id. ¶ 132. BSC's Report of Form 10-K for year ended December 31, 2004, uses very similar language.

Lead Plaintiff asserts that the Defendants sold substantial shares of BSC during the class period, while knowingly or recklessly engaging in acts that operated as a fraud and deceit upon Lead Plaintiff and other members of the Class. Lead Plaintiff, on behalf of itself and others similarly situated, advances two causes of action: (1) violations of Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and (2) violations of Section 20(a) of the Exchange Act.

Discussion

I. Legal Standards

A. Motion to Dismiss

In considering a motion to dismiss for failure to state a claim under Fed. R. Civ. P. 12(b)(6), the court takes all well-pleaded facts stated in the complaint as true, and draws all reasonable inferences in favor of the plaintiff.[41] The court may consider the entirety of relevant documents that are integral to or relied upon in the complaint without converting the motion to dismiss into one for summary judgment.[42]

The court will not credit "bald assertions, unsupportable conclusions, and opprobrious epithets."[43] A motion to dismiss a complaint under Fed. R. Civ. P. 12(b)(6) will be granted only when "it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief."[44]

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[41] Langadinos v. Am. Airlines, Inc., 199 F.3d 68, 69 (1st Cir. 2000).

[42] In re Credit Suisse-AOL Sec. Litig., 465 F. Supp. 2d 34, 38 (D. Mass. 2006) (citation omitted).

[43] Educadores Puertoriquenos en Accion v. Hernandez, 367 F.3d 61, 67 (1st Cir. 2004) (citation omitted).

[44] Leet v. Cellco P'ship, 480 F. Supp. 2d 422, 427-28 (D. Mass. 2007) (quoting Conley v. Gibson, 355 U.S. 41, 45-46 (1957)).

B. Heightened Standard Under the PSLRA

The Private Securities Litigation Reform Act ("PSLRA") requires that a complaint alleging securities fraud based on misstatements or omissions of material fact specify "each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed."[45]

The PSLRA also requires that the complaint "state with particularity facts giving rise to a strong inference" that the defendant acted with scienter.[46] The Supreme Court defines scienter as "a mental state embracing intent to deceive, manipulate, or defraud."[47]

C. Securities Fraud

Section 10(b) of the Securities Exchange Act of 1934 makes it unlawful to "use or employ, in connection with the purchase or sale of any security . . . any manipulative or deceptive device or contrivance in contravention of" rules promulgated by the SEC.[48] Rule 10b-5, which is promulgated under Section 10(b), prohibits making any untrue statement of material fact or omitting a material fact that is necessary to correct an otherwise misleading statement.[49] A 10-b5

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[45] 15 U.S.C. § 78u-4(b)(1) (2007).

[46] 15 U.S.C. § 78u-4(b)(2); In re Cabletron Sys., Inc., 311 F.3d 11, 28 (1st Cir. 2002) (the complaint must "state with particularity facts that give rise to a strong inference of scienter rather than merely a reasonable inference." (internal quotation omitted)); Credit Suisse-AOL, 465 F. Supp. 2d at 39.

[47] Greebel v. FTP Software, Inc., 194 F.3d 185, 194 (1st Cir.1999) (quoting Ernst & Ernst v. Hochfelder, 425 U.S. 185, 193 n.12 (1976)).

[48] 15 U.S.C. § 78j(b).

[49] 17 CFR § 240.10b-5 (2007);

complaint should not be judged on the "general flavor" of the collective challenged statements.[50] Instead, each alleged material omission or misstatement shall be viewed independently.[51]

The elements of securities fraud are: (1) a false statement or omission of material fact, (2) made with scienter, (3) in connection with the purchase or sale of a security, (4) upon which plaintiff relied, (5) an economic loss suffered by plaintiff, and (6) caused by the misrepresentation or omission.[52]

II. Analysis

A. Civil lawsuit with Medinol

In its Consolidated Amended Complaint, Lead Plaintiff alleges that during the Class Period, Defendants duped the investment community with a series of misleading statements and omissions about BSC's ongoing litigation with Medinol. Lead Plaintiff charges that Defendants downplayed the seriousness of the Medinol litigation despite knowledge that the litigation would end poorly for BSC. Ultimately, BSC settled with Medinol for $750 million.

As discussed below, BSC fulfilled its disclosure requirements regarding the Medinol litigation. In another securities fraud case before Judge Woodlock, plaintiffs alleged that the defendant corporation made affirmatively misleading statements about its prospects in a pending civil trial for patent infringement where the company knew with a "high degree of certainty" that

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[50] In re Boston Tech., Inc. Sec. Litig., 8 F. Supp. 2d 43, 55 (D. Mass. 1998).

[51] Id. ("10b-5 allegations must be organized into discrete units that are, standing alone, each capable of evaluation.") (quoting Shapiro v. UJB Fin. Corp., 964 F.2d 272, 284 (3d Cir. 1992)).

[52] Dura Pharms., Inc. v. Broudo, 544 U.S. 336, 341 (2005).

it would receive an adverse jury verdict, which would adversely affect the company's business.[53] When the company lost the jury trial, shareholders filed suit. In granting a motion to dismiss in that case, the court held that the company was only obligated to mention the litigation in general descriptive terms, as required by Item 103 of Regulation S-K.[54] But the company "was not obligated to predict the outcome or estimate the impact" of the litigation.[55] The court also noted that "[w]hile a company that chooses to reveal material information, even though it had no duty to do so, must disclose the whole truth, it need not disclose everything it knows; rather, the company is required only to make additional disclosures to keep the information from being materially misleading."[56]

Similarly, in the case now before this court, BSC met the requirements of Item 103 of Regulation S-K by disclosing the potential risk of the pending Medinol litigation. BSC's Form

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[53] See In re SeaChange Int'l, Inc., No. 02-12116-DPW, 2004 WL 240317, at *7 (D. Mass. Feb. 6, 2004).

[54] Item 103 of Regulation S-K establishes the requirements a company must follow in disclosing pending litigation. Item 103 states the following:

> Describe briefly any material pending legal proceedings, other than ordinary routine litigation incidental to the business, to which the registrant or any of its subsidiaries is a party or of which any of their property is the subject. Include the name of the court or agency in which the proceedings are pending, the date instituted, the principal parties thereto, a description of the factual basis alleged to underlie the proceeding and the relief sought. Include similar information as to any such proceedings known to be contemplated by governmental authorities.

17 C.F.R. § 229.103 (2007).

[55] Seachange, 2004 WL 240317, at *8 ("[The prospectus] contained no statements suggesting that SeaChange would prevail in the litigation or implying that the impact of the litigation on the company would be positive.").

[56] Id.

10-K and BSC's public filings expressly disclosed that "the Company's performance may be effected by . . . The impact of stockholder, patent, product liability, Medinol Ltd. and other litigation . . . ."[57] Having met this requirement, BSC was under no duty to inform the investment community of its own internal assessments of its prospects for settling the Medinol litigation.

Nor does BSC face liability for the results of the Medinol litigation merely because the settlement required BSC to pay Medinol millions of dollars. As the Second Circuit has noted, loss resulting from the materialization of a disclosed risk does not support a claim of securities fraud.[58] Here, BSC repeatedly informed the investment community that Medinol had filed suit against BSC and was seeking "monetary and injunctive relief, as well as an end to the Company's right to distribute Medinol stents and to gain access to certain Company intellectual property."[59]

Lead Plaintiff also fails to allege with particularity any actionable misstatement regarding the Medinol litigation. The challenged statements cannot serve as the basis for a securities claim

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[57] CAC ¶ 61.

[58] Lentell v. Merrill Lynch & Co., Inc., 396 F.3d 161, 173 (2d Cir. 2005) (requiring in a securities fraud case that "the loss be foreseeable *and* that the loss be caused by the materialization of the concealed risk") (emphasis in original)
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[59] App. Public Rs., Ex. A, p. 41; Ex. B, p. 67; Ex. C, p. 65.

because they are corporate puffery,[60] statements of truth, or forward looking statements.[61]

This court need not consider BSC's April 5, 2001 press release that Medinol's claims against BSC "have no merit"[62] because that statement occurred two years prior to the commencement of the class period, and statements made before the beginning of the class period cannot serve as the basis for liability.[63]

The statements in Donovan's December 2, 2004, press release do not support a claim upon which relief can be granted. This statement was merely a condensed version of the district court's summary judgment opinion, which had been issued earlier that day. According to the press release, the Medinol litigation "is essentially a breach of contract case, which alleges 'grandiose estimates of damage' that are unlikely to succeed."[64] This statement is inactionable because it is not false, misleading, or made with scienter. The district court stated that

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[60] Statements of corporate puffery are immaterial as a matter of law. Rosenbaum Capital LLC v. Boston Commc'ns Group, Inc., 445 F. Supp. 2d 170, 176 (D. Mass. 2006) (quoting Shaw v. Digital Equip. Corp., 82 F.3d 1194, 1217 (1st Cir.1996) ("[C]ourts have demonstrated a willingness to find immaterial as a matter of law a certain kind of rosy affirmation commonly heard from corporate managers and numbingly familiar to the marketplace-loosely optimistic statements that are so vague, so lacking in specificity, or so clearly constituting the opinions of the speaker, that no reasonable investor could find them important to the total mix of information available.")).

[61] A person is not liable for any forward-looking statement that is identified as forward-looking and "is accompanied by meaningful cautionary statements identifying important factors that could cause actual results to differ materially . . . ." 15 U.S.C. § 78u-5(c)(1)(A).

[62] CAC ¶ 59.

[63] See In re Ibis Tech. Sec. Litig. 422 F. Supp. 2d 294, 313 n.19 (D. Mass. 2006) (citing In re Int'l Bus. Mach. Corp. Sec. Litig., 163 F.3d 102, 107 (2d Cir. 1998) ("A defendant, however, is liable only for those statements made during the class period.")). The court also discards Defendant Tobin's April 11, 2001, statement on identical grounds.

[64] CAC ¶ 68

"[e]ssentially, this is a breach of contract case . . . The parties have strained to enlarge this case, alleging in their complaint and counterclaims many varieties of tort and grandiose estimates of damage. It is unlikely that these claims can succeed . . . ."[65]

Lead Plaintiff also challenges the following statements:

- "[the New York litigation with] Medinol, that thing has been brought down to this thing which is a contract dispute."[66]

- "[I]ts not a patent issue, it's not an intellectual property issue, it's primarily a straight out contract, breach of contract issue."[67]

Neither of these statements support a claim of securities fraud because they were both accurate. In the New York litigation between Medinol and Boston Scientific, the district court dismissed Medinol's claim for misappropriation of trade secrets, leaving the breach of contract claim as the central remaining dispute.[68] Although some non-contract claims remained, the judge stated that "[e]ssentially, this is a breach of contract case . . ." and "[m]any of Medinol's and Boston Scientific's claims against each other are . . . dismissed. A core number, largely involving their disputed contentions as to their contractual relations, remain for trial."[69] Accordingly, there is no basis to believe that Defendants' statements were false, nor that they knew the statements were false when made.

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[65] Medinol Ltd. v. Boston Scientific Corp., 346 F. Supp. 2d 575, 627 (S.D.N.Y. 2004).

[66] CAC ¶ 64.

[67] Id. ¶ 65.

[68] See Medinol, 346 F. Supp. 2d at 606.

[69] Id. at 627.

At oral arguments, counsel for the Lead Plaintiff conceded that the claims involving the Medinol litigation were not his strongest. "[I]n the context of the allegations set out in the complaint, there are some that are obviously strong and some that are not as strong. I think the Medinol question is one that is close to the wire."[70]

Counsel for Lead Plaintiff rely heavily on Defendant Tobin's private remark to Medinol representatives that his company was run by a bunch of "crooks" as a basis for a securities fraud claim.[71] At oral arguments, counsel took the position that "[h]ad Mr. Tobin not said anything, . . . this [claim about the Medinol litigation] would be a very, very difficult case."[72]

Defendant Tobin's remarks that his company had been run by "crooks" and that he was "ashamed to represent such a dishonest company" suggest that Tobin thought poorly of his predecessors, but are insufficient to support a claim of securities fraud. Defendant Tobin was not addressing the legal merits of the Medinol litigation because he made these remarks in 2000, and the litigation didn't begin until 2001. And his private remarks, made three years prior to the beginning of the Class Period, did not mean that Defendants knew that they would incur massive liability from the Medinol litigation and should inform the market while the litigation was still pending.

Lead Plaintiff fails to allege sufficient facts about the Medinol litigation to survive a motion to dismiss. Because this court has determined that the complaint does not identify an actionable misstatement or omission regarding Medinol, it need not consider Defendants'

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[70] Mot. Dismiss Hr'g Tr. 5:1-5, Jan. 30, 2007 (Paper #65).

[71] See CAC ¶ ¶ 57, 62.

[72] Mot. Dismiss Hr'g Tr. 7:14-15, Jan. 30, 2007.

alternative argument that Lead Plaintiff's claim fails because the truth about the Medinol litigation was on the market.

B. Department of Justice investigation

Lead Plaintiff charges that Defendants misled the investment community about the ongoing DOJ investigation. This claim fails for many of the same reasons that the claims about the Medinol litigation fail. BSC fulfilled its obligations by disclosing the potential risk of an adverse outcome in the DOJ investigation in BSC's 10-K filings during the class period. The form 10-K stated that "[t]here can be no assurance that the investigation will result in an outcome favorable to the Company . . . ."[73] The public filings also stated that "two senior officials have been advised that they are targets of the federal grand jury investigation"[74] and that "the Company's performance may be effected by: . . . the ultimate outcome of the U.S. Department of Justice investigation."[75]

Defendants had no duty to confess guilt. "The federal securities laws do not require a company to accuse itself of wrongdoing."[76] BSC had a duty to disclose the investigation, which

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[73] App. Public Rs., Ex. A, p. 42, Ex. B, p. 68-69, Ex. C, p. 67.

[74] Id.

[75] CAC ¶ 61.

[76] In re Citigroup, Inc. Sec. Litig., 330 F. Supp. 2d 367, 377 (S.D.N.Y. 2004) (finding that plaintiff's claim that Citigroup violated securities laws by failing to disclose that its revenues were derived from allegedly unsustainable and illegitimate sources, including Enron-related activities, did not support a section 10(b) action); see also Iron Workers Local 16 Pension Fund v. Hilb Rogal & Hobbs Co., 432 F. Supp. 2d 571, 586 (E.D.Va. 2006) (holding that defendants in securities fraud case had no duty to disclose that defendant insurance company employed practices which illicitly and improperly relied on non-standard commissions). That court also noted that "Rule 10b-5 was not intended to provide shareholders with an avenue for relief against executives for alleged illegal practices or corporate mismanagement. . . ." Id. at 586 (quoting

it did. Although Defendants had a duty to disclose all underlying material facts that would adversely affect its business, that duty did not extend to pronouncing wrongdoing while the DOJ investigation was ongoing.[77]

BSC's disclosures of the ongoing DOJ investigation were also consistent with SEC regulations.[78] SEC proxy rules require additional disclosure where a director or executive officer was convicted in a criminal proceeding or is a named subject of a pending criminal proceeding.[79] But neither of these scenarios was present. And as another district court has noted, "the SEC's proxy disclosures do not require a company's management to confess guilt to uncharged crimes or to accuse itself of antisocial or illegal policies. . . . There is no reason why a different rule should apply under § 10(b)"[80]

Roeder v. Alpha Industries Corp., upon which Lead Plaintiff relies for the proposition that Defendants had a duty to disclose additional information about the DOJ investigation, is inapposite.[81] There, the Defendant corporation did not disclose that one of its vice presidents

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Galati v. Commerce Bancorp, Inc., No. 04-3252, 2005 WL 3797764, at *8 (D.N.J. Nov. 7, 2005) (unpublished));

[77] See Ballan v. Wilfred Am. Educ. Corp., 720 F. Supp. 241, 249 (E.D.N.Y. 1989) (internal quotations omitted) (holding in securities fraud case that defendants who were the subject of criminal investigation were not bound to predict the likelihood that they would be indicted, but were required to disclose material facts that would potentially endanger the company's future financial performance). In that case, the Defendants were indicted, and the court determined that whether the facts underlying the indictment were material and thus needed to be disclosed was a question for the jury.

[78] See 17 C.F.R. § 229.401(f)(2).

[79] Id.

[80] Ballan, 720 F. Supp. at 249.

[81] See 814 F.2d 22 (1st Cir. 1987).

would be indicted for bribery, and the Court of Appeals found that such information could be material.[82] In contrast, BSC repeatedly disclosed that it was under investigation by the DOJ, and no executives were ever indicted.

Lead Plaintiff's claim also falls short because it fails to allege loss causation, which requires that the loss be caused by a concealed risk.[83] Here, Lead Plaintiff's loss was caused by the materialization of a risk that BSC had adequately disclosed.

Lead Plaintiff asserts that the statement that BSC *may* be adversely effected by the DOJ investigation was materially false because Defendants knew that the DOJ investigation had merit and that BSC *would* be adversely effected by the DOJ investigation. This argument is unpersuasive. Lead Plaintiff fails to allege facts that create a strong inference that the challenged statement was made with scienter. No criminal charges were ever filed, the grand jury did not return an indictment, and the settlement did not involve any admission of liability or wrongdoing by BSC.

Defendant Tobin's comment that, "We believe that Boston Scientific and its employees acted legally, responsibly and appropriately at all times"[84] is also not actionable. The challenged statement fails because Defendant Tobin's statement is one of opinion and "no reasonable investor could find [it] important to the total mix of information available."[85] Statements of opinion are actionable where the plaintiff pleads facts to indicate that the speaker did not actually

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[82] Id. at 25.

[83] See Lentell, 396 F.3d at 173.

[84] CAC ¶ 83.

[85] See Shaw, 82 F.3d at 1217.

believe the statement.[86] But here, Lead Plaintiff fails to meet this standard. The settlement with DOJ did not require BSC to admit any liability or wrongdoing, and Lead Plaintiff has not alleged facts to create a strong inference that the Defendant did not believe his own words. Defendant Tobin's private remark that his company had been run by "crooks," which he made in 2000 to Medinol officials carries no probative weight as to what he thought of the DOJ investigation, and is insufficient to create a strong inference that his 2005 statement regarding the DOJ investigation was subjectively false.

Lead Plaintiff also challenges the following statement made during a July 22, 2003 analyst call about the NORS stent and DOJ investigation: "There's never been any assertion by a patient or physician that the product was anything but okay . . . There's never been any assertion of harm to a patient, by a patient or a physician[.]"[87] This statement is also inactionable because Lead Plaintiff fails to allege facts to create a strong inference that Defendants knew that the statement was false when made. The DOJ press release, stated that "[t]his case does not involve any risk to those patients who had one of these stents implanted in their bodies. The issue is not, and was never, whether the stent performed properly."[88]

Defendants knew that the DOJ investigation had merit, Lead Plaintiff asserts, because BSC executives, none of whom are the Defendants in this case, invoked their Fifth Amendment rights when asked in depositions about the Medinol litigation. Lead Plaintiff's position is unsupported by precedent. The privilege against self-incrimination in the Fifth Amendment,

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[86] In re Credit Suisse First Boston Corp., 431 F.3d 36, 47 (1st Cir. 2005).

[87] CAC ¶ 81

[88] App. Public Rs., Ex. W, p. 2.

"while sometimes 'a shelter to the guilty,' is often 'a protection to the innocent."[89] And the Fifth Amendment also guarantees a defendant that no adverse inferences may be drawn from his exercise of this right.[90] Accordingly, whether BSC executives invoked their Fifth Amendment rights has no bearing on the case currently before the court.

C. Rush of TAXUS Stents to Market

Lead Plaintiff contends that Defendants knew about problems with the TAXUS stent prior to the three 2004 product recalls, withheld this information from the public, and made misleading statements. To support its claim that Defendants knew that TAXUS was fundamentally flawed, Lead Plaintiff points to the major deficiency letter that the FDA wrote BSC in 2003, adverse reports from doctors in 2003 and 2004, and a manufacturing change that BSC implemented in 2004.

The major deficiency letter, which BSC received in September 2003, put BSC on notice that the FDA needed more information before it could proceed in evaluating TAXUS for FDA approval.[91] BSC provided this information, and on March 4, 2004, the FDA approved TAXUS for release in the United States.[92] The FDA's request for additional information, which BSC supplied, does not support Lead Plaintiff's contention that Defendants knew that TAXUS was

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[89] Carter v. Kentucky, 450 U.S. 288, 300 (1981) (quoting Murphy v. Waterfront Comm'n, 378 U.S. 52, 55 (1964)).

[90] United States v. Brand, 80 F.3d 560, 567 (1st Cir. 1996) (citing Carter, 450 U.S. at 305).

[91] See 21 C.F.R. § 814.37(b) ("A major deficiency letter informs the applicant that its PMA [Premarket Approval Application] lacks significant information needed for FDA to complete the scientific review of, and render a final decision on, the PMA.").

[92] CAC ¶ 92.

defective, or that TAXUS was "broken on day one."[93] Rather, the letter was a step in the FDA approval process which BSC had no duty to disclose.[94]

Lead Plaintiff asserts that Defendants also learned that TAXUS was defective from adverse reports from doctors that it received prior to the TAXUS recalls. After TAXUS's European release in the spring of 2003, BSC received a number of complaints from European doctors that the balloon would not deflate after insertion, and that the balloon was sticking.[95] The total number of complaints from European doctors was very small, roughly forty out of 350,000 TAXUS stents, and BSC attributed these problems to lack of doctor familiarity with TAXUS, rather than product defect.[96] According to BSC, these complaints subsided as doctors became comfortable with TAXUS.[97]

After BSC's domestic release of TAXUS in March 2004, it received some complaints from American doctors. BSC made statements that these new complaints about TAXUS were equivalent to the complaints it received in Europe.[98] Lead Plaintiff asserts that these statements were false and that the Defendants knew that the problems in Europe and in America were the

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[93] Mot. Dismiss H'rg Tr. 24:9-12, Jan. 30, 2007.

[94] See In re Alkermes Sec. Litig., No. 03-12091-RCL, 2005 WL 2848341, at *16 (D. Mass. 2005) ("The Defendants had no duty to disclose that the FDA had requested additional studies because they had never guaranteed FDA approval.").

[95] CAC ¶ 93.

[96] Id.

[97] Id.

[98] "[Donovan] said a few doctors in Europe reported similar problems when TAXUS was initially approved for use there last year, but the complaints ended as doctors became more comfortable with the stents." Id.

result of a flawed product rather than doctor unfamiliarity. But the Consolidated Amended Complaint provides little in the way of facts to support this claim. Lead Plaintiff pleads no facts to suggest that the complaints BSC received from American doctors were different than those it received from European doctors. And Lead Plaintiff does not charge falsity in Defendants' remarks that the complaints from European doctors declined over time. If the TAXUS stents released in Europe were truly defective, the rate of complaints should have remained constant.

The European doctors' diminishing number of complaints is consistent with Defendants' stated belief that the complaints derived from doctors becoming accustomed to the product rather than product defect. This is also consistent with Defendants' remarks in the spring of 2004 that the complaints they were receiving in America were similar in nature to those received from Europe. Lead Plaintiff does not plead facts to provide a strong inference that Defendants knew that these statements were false when made. Accordingly, such remarks do not support a claim of securities fraud.[99]

The court notes that BSC disclosed that it received complaints and that it was reviewing them. In its Report on Form 10-Q for the period ending March 31, 2004, which was released on May 7, 2004, BSC stated that it was "reviewing a limited number of reports related to balloon withdrawal difficulty during TAXUS angioplasty procedures."[100]

Lead Plaintiff also points to the manufacturing change that BSC implemented prior to the domestic launch of TAXUS as evidence that Defendants knew that TAXUS was defective. Lead Plaintiff alleges that the manufacturing change was "material information that the market had a

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[99] See 15 U.S.C. 78u-4(b)(2).

[100] CAC ¶ 93.

right to know."[101] In hindsight, as discussed below, it appears that this manufacturing change may indeed have been material. But a plaintiff in a securities case "does not satisfy the requirements of Rule 9(b) merely by pleading fraud by hindsight."[102]

A manufacturing change does not necessarily mean that a product is defective, or that a company knows that a product is defective. Companies frequently adjust and change their products, and no rule requires a company to inform the public every time it modifies its manufacturing process. Such changes are often for purely innocuous reasons, such as to enhance or fine tune an already successful product.

Here, the manufacturing change was conducted with the knowledge and approval of the FDA, and at a time when BSC had received only a limited number of complaints from Europe which had tapered off after the product's release. And Lead Plaintiff does not dispute that BSC's manufacturing change occurred before it launched TAXUS in the United States and that the change "would have been submitted whether [BSC] got a complaint or not."[103] Under these circumstances, Lead Plaintiff fails to allege facts that provide a strong inference that at the time of the manufacturing change, Defendants knew that TAXUS was defective or that the product would later be recalled.

In the summer of 2004, BSC recalled a total of 99,200 stents.[104] The recalls were limited,

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[101] Id. ¶ 99.

[102] Gross v. Summa Four, Inc., 93 F.3d 987, 991 (1st Cir. 1996) (internal quotations and citations omitted).

[103] CAC ¶ 98.

[104] BSC recalled 200 stents on July 2, 2004, 96,000 stents on July 16, 2004, and 3,000 stents on August 4, 2004. CAC ¶¶ 97, 100,102.

and only applied to a fraction of the TAXUS stents released on the domestic market. After the recalls, BSC disclosed in its Form-10K that it had implemented an FDA-approved modification to the manufacturing process for TAXUS and that this measure, in combination with other measures, "will be effective in reducing the occurrence of balloon non-deflation."[105] This statement in the Form 10-K connects the manufacturing change with balloon non-deflation. But a "reasonable inference [of scienter] is insufficient to survive a motion to dismiss."[106] Though BSC may have been able to say after the recalls that the manufacturing change would help redress the problem that led to the recalls, it does not follow that BSC, or its executives, knew at the time of the manufacturing change that the problem was sufficiently bad so as to lead to a recall. For this reason, the asserted facts do not create a strong inference that TAXUS was defective before the manufacturing change, or that Defendants knew that TAXUS was defective.

Lead Plaintiff also takes issue with Defendant LaViolette's July 29, 2004, remarks that BSC had identified and fixed the problem with TAXUS. Shortly after LaViolette's statement, BSC initiated a third TAXUS recall of 3,000 stents. But no liability exists where a plaintiff's claim rests on the assumption that the defendants "must have known of the severity of their problems earlier because conditions became so bad later on."[107] Here, Lead Plaintiff fails to allege facts that provide a strong inference that Defendant LaViolette knew that an additional recall was necessary or that his remarks were false when he made them. Accordingly, Defendant

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[105] Aff. of Anne T. Regan in Opp. to Defs.' Mot. to Dismiss the Consolidated Am. Compl. (Paper #57), Ex. D, Excerpts of August 9, 2004 Form 10-Q, at 30.

[106] Greebel v. FTP Software, Inc., 194 F.3d 185, 197 (1st Cir.1999).

[107] In re Boston Technology, Inc. Sec. Litig., 8 F. Supp. 2d 43, 53 (D. Mass. 1998) (quoting Serabian v. Amoskeag Bank Shares, Inc., 24 F.3d 357, 367 (1st Cir. 1994)).

LaViolette's remark is inactionable fraud by hindsight.

Plaintiff asserts that its complaint resembles the complaint before Judge Young in Allaire and therefore does not rely on classic 'fraud by hindsight.'[108] In that securities fraud case, the court denied a motion to dismiss where a software manufacturer made many positive statements about its computer software and then released software that was so defective that it was inoperable.[109] The court held that the product was so severely flawed that it supported the strong inference that the product had also been flawed at the time that defendants made positive statements about it.[110] The facts of Allaire are plainly distinguishable. There, the product was such a complete dud that the court noted that it would have been "inconceivable" that management could not have known that the program did not work.[111] Here, the TAXUS stent was not inoperable and only a fraction of the product was ever recalled.

D. FDA investigations and warnings

Next, Lead Plaintiff contends that Defendants made intentionally misleading statements about BSC's quality control and failed to inform the market about the three FDA warning letters BSC received in the Spring and Summer of 2005. The warning letters outlined significant deficiencies or regulatory problems that inspectors discovered at BSC plants.

It is this court's view that the FDA letters were not material and that BSC had no

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[108] See Lead Pl.'s Mem. of Law in Opp. to Defs.' Mot. to Dismiss the Consolidated Amended Compl. 14 (Paper # 56).

[109] In re Allaire Corp. Sec. Litig., 224 F. Supp. 2d 319, 329 (D. Mass. 2002).

[110] Allaire, 224 F. Supp. 2d at 330.

[111] Id. at 329.

affirmative duty to disclose them.[112] In reaching this conclusion, this court notes that the three letters were "informal and advisory,"[113] resulted in no enforcement action against the company and involved only three of BSC's twenty-six facilities.

Other courts have dismissed similar securities fraud claims involving failure to disclose FDA warning letters. In Acito v. IMCERA Group, Inc., the Second Circuit affirmed a district court's determination that a series of FDA warning letters were not material and did not need to be disclosed.[114] In upholding the district court's dismissal of a Section 10(b) claim, the court noted that the defendant corporation was a world-wide company that engaged in heavily regulated businesses and that it would be "unduly burdensome and impractical to publicly

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[112] The First Circuit has defined materiality as follows:

> The boundaries of materiality in the securities context are clearly enunciated in our case law. The mere fact that an investor might find information interesting or desirable is not sufficient to satisfy the materiality requirement. Rather, information is "material" only if its disclosure would alter the "*total mix* " of facts available to the investor and "if there is a *substantial likelihood* that a reasonable shareholder would consider it important" to the investment decision.

Lucia v. Prospect St. High Income Portfolio, Inc., 36 F.3d 170, 175 (1st Cir. 1994) (quoting Milton v. Van Dorn Co., 961 F.2d 965, 969 (1st Cir. 1992)). Generally, materiality is a question of fact that proceeds to the jury, rather than being resolved by the court on a motion to dismiss. In re Cabletron Sys., Inc., 311 F.3d 11, 34 (1st Cir. 2002). But the court must determine whether the complaint presents a "plausible jury question of materiality." Id.

Having concluded that the warning letters were not material, this court need not address Defendants' argument that the warning letters were also not actionable because they were publicly available on the FDA's website.

[113] App. Public Rs., Ex. R, 4-2 ("A Warning Letter is informal and advisory. It communicates the Agency's position on a matter, but it does not commit FDA to taking enforcement action.").

[114] 47 F.3d 47, 52 (2d Cir. 1995).

disseminate the results of every inspection of every plant."[115] Likewise, BSC is a global corporation that operates in a regulated industry.

And in Anderson v. Abbott Laboratories, a district court dismissed a Section 10(b) claim where defendant, a medical systems manufacturing company, did not disclose an FDA warning letter.[116] In doing so, the court noted that "[t]here is nothing magical about [an FDA] warning letter. Although the language sounds ominous, it really is rather boilerplate."[117]

This case is distinguishable from Malozzi v. Zoll Medical Corp, upon which Lead Plaintiff relies. In that case, the district court denied Defendants' motion to dismiss a Section 10(b) claim where defendants did disclose an FDA warning letter, but failed to disclose a series of FDA reports, disguised the scope of an ongoing FDA investigation, and made false and misleading statements about an FDA-prompted product recall.[118] Here, the FDA warning letters were unrelated to any product recall or enforcement report, and resulted in no adverse action against BSC.

Lead Plaintiff takes issue with statements that BSC implemented "state-of-the-art quality systems," that its Glen Falls facility is "world class," and "cutting edge" and that within "the device community . . . [BSC] basically ha[s] a set of cards that really are second to no one

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[115] Id. at 52-53.

[116] Anderson v. Abbott Labs.,140 F. Supp. 2d 894, 902 (N.D.Ill. 2001) ("Given the repeating cycle of inspections, findings and negotiations, without any FDA sanctions, plaintiffs must give us a reason to believe this time was different-something that shows Abbott's prospects had genuinely changed or something from the FDA that said, 'This time we're serious.' This plaintiffs have failed to do.").

[117] Id. at 902.

[118] Mallozzi v. Zoll Med. Corp., No. 94-11579-NG, 1996 WL 392146, at *4-5 (D. Mass. Mar. 5, 1996).

else."[119] Every company praise its products and its objectives, and these statements are nothing more than corporate puffery.[120] No reasonable investor would find these remarks important in the total mix of information available.[121] "'[A] claim that a fraud was perpetrated on the *market* can draw no sustenance from allegations that defendants made overly-optimistic statements, if those statements are ones that any reasonable investor (ergo, the market) would easily recognize as nothing more than a kind of self-directed corporate puffery. The market is not so easily duped, even granted that individual investors sometimes are.'"[122]

In addition, the challenged statement from BSC's April 5, 2005, press release that touted BSC's "rigorous laboratory testing" fails to support a securities fraud claim because it was issued prior to the receipt of the May 18, 2005, FDA warning letter.

E. Violations of Section 20(a) of the Exchange Act

Lead Plaintiff also asserts claims for violations of Section 20(a) of the Exchange Act. This provision authorizes a cause of action against any person who exerts direct or indirect control over a corporation that acts in violation of the securities laws.[123]

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[119] CAC ¶ 115.

[120] See In re Ford Motor Co. Sec. Litig., 381 F.3d 563, 570 (6th Cir. 2004) (finding statements such as "at Ford quality comes first," "Ford has its best quality ever," "Ford is a worldwide leader in automotive safety," and "Ford has made quality a top priority" inactionable. In reaching this conclusion, the court noted that the statements "are either mere corporate puffery or hyperbole that a reasonable investor would not view as significantly changing the general gist of available information, and thus, are not material, even if they were misleading.").

[121] See Shaw, 82 F.3d at 1217.

[122] In re Pharms., Inc. Sec. Litig., No. 04-12581-GAO, 2007 WL 951695, at *8 (D. Mass. Mar. 28, 2007) (quoting Shaw, 82 F.3d at 1218.).

[123] See 15 U.S.C. § 78t(a); In re Parametric Tech. Corp., 300 F. Supp. 2d 206, 223 (D. Mass. 2001).

But as previously detailed, Lead Plaintiff has failed to adequately allege a Section 10(b) violation. Accordingly, Lead Plaintiff's Section 20(a) claim for control person liability also fails.[124]

Conclusion

For these reasons, Defendants' Motion to Dismiss [#50] is ALLOWED. This case is closed. An order has issued.

/s/ Joseph L. Tauro
United States District Judge

[124] Parametric, 300 F. Supp. 2d at 224 ("[W]here there is no liability under Section 10(b), it must follow that there is none under Section 20(a), regardless of an individual defendant's position or influence within a company.").

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1:05-cv-11934-JLT Shankar v. Boston Scientific Corporation et al
Joseph L. Tauro, presiding
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		Fredericus A. Colen (Defendant) James R. Tobin (Defendant) Lawrence C. Best (Defendant) Paul A. Laviolette (Defendant) Stephen F. Moreci (Defendant)
Theodore M. Hess-Mahan Hutchings, Barsamian, Cross and Mandelcorn, LLP 110 Cedar St. Wellesley Hills, MA 02481 781-431-2231 781-431-8726 (fax) thess-mahan@hutchingsbarsamian.com Assigned: 11/21/2005 TERMINATED: 01/05/2007 LEAD ATTORNEY ATTORNEY TO BE NOTICED	representing	City of Pontiac Policemen's and Firemen's Retirement System (Plaintiff) PRO SE
		Locals 302 and 612 of the International Union of Operating Engineers-EMployers COnsutrction Industry Retirement Trust (Plaintiff) PRO SE New England Health Care Employees Pension Fund (Plaintiff) PRO SE Plumbers and Pipefitters Local No. 502 & 633 Pension Trust Fund (Plaintiff) PRO SE
Miranda Hooker Wilmer Cutler Pickering Hale and Dorr LLP 60 State Street Boston, MA 02109 617-526-6000 617-526-5000 (fax) miranda.hooker@wilmerhale.com Assigned: 10/31/2005 LEAD ATTORNEY ATTORNEY TO BE NOTICED	representing	Boston Scientific Corporation (Defendant)
		Fredericus A. Colen (Defendant) James R. Tobin (Defendant) Lawrence C. Best (Defendant) Paul A. Laviolette (Defendant) Stephen F. Moreci (Defendant)
John C. Martland Martland & Brooks LLP Stonehill Corporate Center, Suite 500 999 Broadway Saugus, MA 01906 617-742-9700 617-742-9701 (fax) jcmartland@gilmanpast	representing	John Ryan (Consolidated Plaintiff)

or.com Assigned: 02/09/2006 LEAD ATTORNEY ATTORNEY TO BE NOTICED		
		Robert L. Garber (Consolidated Plaintiff)
Tricia L. McCormack Lerach Coughlin Stoia Geller Rudman & Robbins Suite 1900 655 West Broadway San Diego, CA 92101 619-231-1058 619-231-7423 (fax) Assigned: 12/21/2005 TERMINATED: 06/14/2006 LEAD ATTORNEY ATTORNEY TO BE NOTICED	rep res ent ing	City of Pontiac Policemen's and Firemen's Retirement System (Plaintiff) PRO SE
		Locals 302 and 612 of the International Union of Operating Engineers-EMployers COnsutrction Industry Retirement Trust (Plaintiff) PRO SE New England Health Care Employees Pension Fund (Plaintiff) PRO SE Plumbers and Pipefitters Local No. 502 & 633 Pension Trust Fund (Plaintiff) PRO SE Police and Fire Retirement System of the City of Detroit (Movant)
Robert C. Moilanen Zimmerman Reed PLLP Suite 501 651 Nicollet Mall Minneapolis, MN 55402 612-341-0400 612-341-0844 (fax) rcm@zimmreed.com Assigned: 12/14/2005 LEAD ATTORNEY ATTORNEY TO BE NOTICED	rep res ent ing	Mississippi Public Employees Retirement System (Plaintiff)
David S. Nalven Hagens Berman Sobol Shapiro LLP One Main Street 4th Floor Cambridge, MA 02142 617-482-3700 617-482-3003 (fax) davidn@hbsslaw.com Assigned: 02/09/2006 LEAD ATTORNEY ATTORNEY TO BE NOTICED	rep res ent ing	Betty C. Meyer (Consolidated Plaintiff)
		Mississippi Public Employees Retirement System (Consolidated Plaintiff)
Kirsten M. Nelson	rep	Boston Scientific Corporation (Defendant)

Shearman & Sterling LLP 599 Lexington Avenue New York, NY 10022-6069 212-848-4320 646-828-4320 (fax) kirsten.nelson@shearman.com Assigned: 04/04/2006 ATTORNEY TO BE NOTICED	representing	Fredericus A. Colen (Defendant) James R. Tobin (Defendant) Lawrence C. Best (Defendant) Paul A. Laviolette (Defendant) Stephen F. Moreci (Defendant) James H. Taylor, Jr. (Defendant) Paul Sandman (Defendant) Peter M. Nicholas (Defendant) Robert G. MacLean (Defendant)
William H. Paine Wilmer Cutler Pickering Hale and Dorr LLP 60 State Street Boston, MA 02109 617-526-6134 617-526-5000 (fax) william.paine@wilmerhale.com Assigned: 10/31/2005 LEAD ATTORNEY ATTORNEY TO BE NOTICED	representing	Boston Scientific Corporation (Defendant)
		Fredericus A. Colen (Defendant) James R. Tobin (Defendant) Lawrence C. Best (Defendant) Paul A. Laviolette (Defendant) Stephen F. Moreci (Defendant)
David Pastor Gilman and Pastor, LLP 225 Franklin Street 16th Floor Boston, MA 02110 617-742-9700 617-742-9701 (fax) dpastor@gilmanpastor.com Assigned: 09/23/2005 LEAD ATTORNEY ATTORNEY TO BE NOTICED	representing	Srinivasan Shankar (Plaintiff)
		Jack Yopp (Consolidated Plaintiff) John Ryan (Consolidated Plaintiff) Robert L. Garber (Consolidated Plaintiff)
Timothy J. Perla Wilmer Cutler Pickering Hale and Dorr LLP 60	represent	Boston Scientific Corporation (Defendant)

State Street Boston, MA 02109 617-526-6696 617-526-6000 (fax) timothy.perla@wilmerhale.com Assigned: 10/31/2005 LEAD ATTORNEY ATTORNEY TO BE NOTICED	ing	
		Fredericus A. Colen (Defendant) James R. Tobin (Defendant) Lawrence C. Best (Defendant) Paul A. Laviolette (Defendant) Stephen F. Moreci (Defendant)
Michael T. Rasnick Shearman & Sterling LLP 599 Lexington Avenue New York, NY 10022 212-848-4000 212-848-7179 (fax) Assigned: 04/05/2006 LEAD ATTORNEY ATTORNEY TO BE NOTICED	rep res ent ing	Boston Scientific Corporation (Defendant)
		Fredericus A. Colen (Defendant) James R. Tobin (Defendant) Lawrence C. Best (Defendant) Paul A. Laviolette (Defendant) Stephen F. Moreci (Defendant)
Anne T. Regan Zimmerman Reed, PLLP Suite 501 651 Nicollet Mall Minneapolis, MN 55402 612-341-0400 612-341-0844 (fax) atr@zimmreed.com Assigned: 12/14/2005 LEAD ATTORNEY ATTORNEY TO BE NOTICED	rep res ent ing	Mississippi Public Employees Retirement System (Plaintiff)
Darren J. Robbins Lerach Coughlin Stoia Geller Rudman & Robbins, LLP Suite 1900 655 West Broadway San Diego, CA 92101 619-231-1058 619-231-7423 (fax) Assigned: 12/21/2005 TERMINATED: 06/14/2006 LEAD ATTORNEY	rep res ent ing	City of Pontiac Policemen's and Firemen's Retirement System (Plaintiff) PRO SE

ATTORNEY TO BE NOTICED		
		Locals 302 and 612 of the International Union of Operating Engineers-EMployers COnsutrction Industry Retirement Trust (Plaintiff) PRO SE New England Health Care Employees Pension Fund (Plaintiff) PRO SE Plumbers and Pipefitters Local No. 502 & 633 Pension Trust Fund (Plaintiff) PRO SE Police and Fire Retirement System of the City of Detroit (Movant)
Samuel H. Rudman Lerach Coughlin Stoia Geller Rudman & Robbins LLP 58 South Service Road Suite 200 Melville, NY 11747 631-369-7100 631-367-1173 (fax) srudman@lerachlaw.com Assigned: 02/07/2006 TERMINATED: 06/14/2006 LEAD ATTORNEY ATTORNEY TO BE NOTICED	representing	City of Pontiac Policemen's and Firemen's Retirement System (Plaintiff) PRO SE
		Locals 302 and 612 of the International Union of Operating Engineers-EMployers COnsutrction Industry Retirement Trust (Plaintiff) PRO SE New England Health Care Employees Pension Fund (Plaintiff) PRO SE Plumbers and Pipefitters Local No. 502 & 633 Pension Trust Fund (Plaintiff) PRO SE
Stephen V. Saia Law Offices of Stephen V. Saia 70 Old Cart Path Lane Pembroke, MA 02359 781-826-8401 775-201-8079 (fax) saialaw@earthlink.com Assigned: 11/21/2005 ATTORNEY TO BE NOTICED	representing	The Warehouse Employees Local 169 & Employers Joint Pension Fund Davis Road & Oakwood Lane Valley Forge, PA 19482 212 483-6000 (Movant)
Thomas M. Sobol Hagens Berman Sobol Shapiro LLP One Main Street 4th Floor Cambridge, MA 02142 617-482-3700 617-482-3003 (fax) Tom@hbsslaw.com Assigned: 12/13/2005 ATTORNEY TO BE NOTICED	representing	Srinivasan Shankar (Plaintiff)
		Betty C. Meyer (Consolidated Plaintiff)

Monika A. Wirtz Wilmer Cutler Pickering Hale and Dorr LLP 60 State Street Boston, MA 02109 617-526-6896 617-526-5000 (fax) monika.wirtz@wilmerhale.com Assigned: 10/31/2005 TERMINATED: 01/31/2007 LEAD ATTORNEY ATTORNEY TO BE NOTICED	representing	Boston Scientific Corporation (Defendant)
		Fredericus A. Colen (Defendant)
		James R. Tobin (Defendant)
		Lawrence C. Best (Defendant)
		Paul A. Laviolette (Defendant)
		Stephen F. Moreci (Defendant)